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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/971,929	10/09/2001	Naoyuki Takano	2185-0577P	2971

7590 03/30/2007  
BIRCH, STEWART, KOLASCH & BIRCH, LLP  
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Falls Church, VA 22040-0747

EXAMINER
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GUDIBANDE, SATYANARAYAN R

ART UNIT	PAPER NUMBER
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1654

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/30/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/971,929	<b>Applicant(s)</b> TAKANO ET AL.	
	<b>Examiner</b> Satyanarayana R. Gudibande	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7, 9-14 and 16-21 is/are pending in the application.
- 4a) Of the above claim(s) 3-5, 7, 16 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 9-14, 17 and 19-21 is/are rejected.
- 7) ☒ Claim(s) 19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's response and amendments to claim filed on 1/23/07 is acknowledged.

As stated in the previous office action dated 10/30/06, Examiner searched the elected species chitosan trisaccharide and diethylenetriaminepentaacetic acid found them free of art.

Examiner extended the search and found art on serum albumin antibody and

diethylenetriaminepentaacetic acid.

Claims 1-5, 7, 9-14 and 16-21 are pending.

Claims 6, 8 and 15 have been canceled.

Claims 3-5, 7, 16 and 18 are withdrawn from further consideration as being drawn to non-elected species.

Claims 1, 2, 9-14, 17 and 19-21 are examined on the merit.

### ***Allowable Subject Matter***

Claim 19 contains allowable subject matter, i.e., claim is drawn to the elected species chitosan trisaccharide that has been found to be free of art, but contains other species chitosan tetra- to deca-saccharide.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 9-14, 17 and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Paik, et al., J. Nucl. Med. 1983, 1158-1163.

In the instant application, applicants claim a process of producing an amide bond that comprises of reacting a compound having an amino group with a polyaminopolycarboxylic acid anhydride in the presence of the polyaminopolycarboxylic acid.

Paik, et al., teaches such a method of amide formation. The reference teaches the preparation of DTPA coupled serum albumin antibody. In the process, Paik, et al., affinity-purified antibody (300  $\mu$ g, 2.0 nmol) was dissolved in 1 ml of 0.1M buffer solution (Hepes buffer at pH 7, phosphate at pH 7, borate at pH 8.6, or bicarbonate at pH 8.2) in a 2.5-ml vial. To the antibody solution was added solid cyclic DTPA anhydride (page 1159, column 2, paragraph 1). However, during the IR (infrared spectroscopy) analysis of the DTPA anhydride, Paik, et al., the IR spectrum showed absorption bands at 1825 and 1780  $\text{cm}^{-1}$ , characteristic stretching vibrations for the **anhydride carbonyl group**. The IR spectrum also showed an absorption at 1640  $\text{cm}^{-1}$  indicating the presence of a **carboxylate group**. The claim limitation that the presence of both polyaminopolycarboxylic acid anhydride and the presence of the polyaminopolycarboxylic acid in the reaction mixture is met by the fact that the anhydride used in the preparation was a mixture of the anhydride and the free acid as shown by the IR analysis. Therefore, this meets claim limitations of claims 1 and 21. Also, during the DTPA conjugation

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reaction, the reaction reduced the pH of buffer solution to 4. due to the hydrolysis of the anhydride that produced four acetic acid molecules (page 1161, column 1, paragraph 1) further affirming the presence of free polyaminocarboxylic acid in the reaction mixture. The reaction was carried out in bicarbonate buffer, pH 8.2 as mentioned above and hence in basic condition that meets one of the limitations of claim 21.


### *Conclusion*

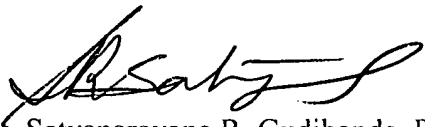
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
ANISH GUPTA  
PRIMARY EXAMINER

  
Satyanarayana R. Gudibande, Ph.D.